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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,900	SCARBOROUGH ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-15,17,18,38-58 and 62-68* is/are pending in the application.

4a) Of the above claim(s) *42,43,51 and 53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-15,17,18,38-41,44-50,52,54-58 and 62-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 10/23/2007.

2. In the reply, the Applicant amended claims 8, 14, 46, 62, 67, 68; cancelled claims 59-61. Claims 42-43, 51, 53 remain withdrawn.

3. The Petition to Correct Inventorship under 37 CFR 1.48(a) filed on 11/27/2006 has been APPROVED. See discussion below.

4. Thus, claims 8-15, 17-18, 38-41, 44-50, 52, 54-58, 62-68 are pending for examination.

Inventorship

5. In view of the papers filed 11/27/2006, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Peter A. Weissman.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 40, 46, 50, 62, 64, 68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 40, 46, 50, 62, 64, 68 inconjunction with their respective independent claims recite that the pain and concordance response data are both inputted separately using a sliding device having a visual analog scale (VAS) from 1-10 and an axis for relative the level of concordance, non-concordance or the concordance and non-concordance of the pain. This is not described at the time of the originally filed application. On pg 17, lns 19-30 "Patient Feedback sub-system", the Applicant discloses:

> *"Patient feedback sub-system 66 receives real-time quantifiable response data of the patient. The response data preferably includes a patient's pain level and concordance and can include data input directly by the patient using, e.g. a squeeze ball or a sliding device correlated to a visual analog scale (VAS) from 0-10* ***and*** *including an axis for relating level of concordance/non-concordance of the pain, and/or observed data such as physiological parameters including electromyographic response data. Other observed data include audiovisual recordings of facial responses such as wincing, grimacing, clenching of the jaw and the like..." (emphasis added)*

8. As disclosed, the Applicant does not have possession of inputting the level of concordance/non-concordance of the pain via the sliding device. The pain level is measuring via the sliding device on a VAS scale of 0-10. The sliding device possess an axis for relating the level of concordance/non-concordance data, but there is no disclosure of a second sliding scale. Thus, when the Applicant now claims inputting both pain level and concordance level separately both via the sliding device, the Applicant has claimed subject matter not in possession upon original filing because the

Applicant has not disclose that the concordance/non-concordance of pain is inputting via a sliding device – merely that the sliding device has an axis. Additionally, the Applicant does not have possession of the subject matter that the axis may the relate level of concordance, non-concordance of the pain. The axis only relates the level of concordance/non-concordance; whereas, the visual analog scale from 0-10 relates the pain level. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 8-13, 41, 44-45, and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Kraft (6370420).

11. In reference to independent claim 8, Kraft discloses a fluid introduction system, comprising: an introducer (14) configured to introduce fluid into a spine of a patient; an operator (18) configured to actuate the introducer to introduce fluid into the spine of the patient; a computer readable medium having code for receiving: fluid introduction data indicative of a fluid introduction parameter (col 3, lns 58-col 4, lns 13); and response data indicative (col 4, lns 13-col 37) of pain level of a response of the patient at a time related to a time of the fluid introduction data; and response data, input separately from the pain level data, indicative of concordance of the response of the patient at the time

related to the time of the fluid introduction data, the concordance data indicating whether the pain level response of the patient is a result of a pain symptom or is a result of pain unrelated to the pain symptom (see discussion below in Response to Arguments).

12. In reference to claims 9-13, 41, 44-45 see (Summary, Figs 1-5; citations above and col 4, lns 66-col 6, lns 26).

13. In reference to independent claim 67, Kraft discloses a fluid introduction system for performing discography diagnosis, comprising: an introducer (14) configured to introduce fluid into a spine of a patient; a computer readable medium having code for receiving: fluid introduction data indicative of a fluid introduction parameter (col 3, lns 58-col 4, lns 13); an pain level of the patient responsive to the fluid introduction data (col 4, lns 13-37), and concordance data, input separately from the pain level data, indicating whether the pain level of the patient is a result of a pain symptom or is a result of pain unrelated to the pain symptom (see discussion below in Response to Arguments), wherein the discography diagnosis is based upon the correlation between the pain level and concordance data and the fluid introduction data (Summary, col 4, lns 66-col 6, lns 26).

14. Claims 14-15, 17-18 and 55-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Hochman et al (6945954). Hochman et al discloses a fluid introduction system, comprising: an introducer (Fig 1) configured to introduce a non-pulsatile flow of fluid into a spine, the introducer having a flow rate-dependent impedance opposing the

introduction of the fluid (Summary); and an operator (18) configured to actuate the introducer, the operator including code to determine impedance data indicative of the flow rate-dependent impedance based upon actuation of the introducer prior to insertion of the introducer into the spine (col 3, lns 54-56; col 4, lns 2-5, 28-47; col 9, lns 28-48; col 10, lns 7-15; col 11, lns 41-62; col 12, lns 48-col 13, lns 16; discussion below in Response to Arguments) and to control the actuation of the introducer based at least in part upon impedance data (col 3, lns 11-col 4, lns 54); wherein using the determined impedance data, the code corrects pressure data by the introduction of fluid and the pressure of fluid within the introducer (col 3, lns 54-56; col 4, lns 2-5, 28-47; col 9, lns 28-48; col 10, lns 7-15; col 11, lns 41-62; col 12, lns 48-col 13, lns 16); wherein the introducer includes an identifier (col 7, lns 10-13; 208) including the impedance data and the operator is configured to receive the impedance data from the identifier of the introducer; wherein the operator includes code to determine the impedance data based upon an actuation of the introducer (col 3, lns 11-col 4, lns 54; Program Listing); further comprising: a pressure sensor (7) configured to provide pressure data indicative of a pressure of fluid present in the introducer; a fluid introduction sensor (208) configured to provide fluid introduction data indicative of at least one of (a) a rate of fluid introduction and (b) an mount of fluid introduced into the portion of the spine (col 3, lns 11-col 4, lns 54); wherein the operator includes code to determine the impedance data based upon the pressure data and the fluid introduction data (col 3, lns 11-col 4, lns 54, Program Listing); wherein the impedance data comprises a gauge of a fluid introduction member, a length of a fluid introduction member, an inner diameter of a

fluid conduit; and a length of a fluid conduit (col 3, lns 11-col 4, lns 54; Program Listing; col 7, lns 10-13; col 9, lns 29-49). Additionally, see discussion below in Response to Arguments.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claim 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft in view of Factor et al (6258042). Kraft discloses the invention substantially as claimed except for expressly disclosing the response data being data inputted directly by the patient using a sliding device. Factor et al teaches that it is known to have a sliding device correlated to a visual analog scale with an axis for relating pain level (Fig 1-2, Summary; Detailed Description of Invention) for the purpose of allowing the patient to indicate the amount and intensity of pain being experienced in discrete incremental intervals. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the manually inputted response data as taught by Kraft with the manually inputted sliding VAS device as taught by Factor et al for the purpose of allowing the patient to indicate the amount and intensity of pain being experienced in discrete incremental intervals.

17. Claims 38-40, 46-50, 52-54, 62-66, 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft in view of Gaston-Johansson (5692500). Kraft discloses the invention substantially as claimed except for expressly disclosing wherein the pain level and concordance data is inputted separately by hand by the patient on a sliding device that is correlated to a visual analog scale (VAS) from 0-10 and includes an axis for relating level of concordance, non-concordance, or concordance and non-concordance of the pain.

18. Gaston-Johansson teaches that it is known to have wherein the pain level and concordance data is inputted separately by hand by the patient on a sliding device that is correlated to a visual analog scale (VAS) from 0-10 (44, 40) and includes an axis for relating level of concordance, non-concordance, or concordance and non-concordance of the pain (66; Figs 1-4; col 2, lns 59-67; Summary; wherein the separate scale 66 in Figs 1-2 and shown in Fig 3 although detailing continuous/noncontinuous pain is fully capable of detailing whether the pain experienced is new or from a previous pain symptom) for the purpose of diagnosing the type and intensity of pain being experienced. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Kraft with the pain level and concordance input as taught by Gaston-Johansson for the purpose of diagnosing the type and intensity of pain being experienced.

19. Claims 38-40, 46-50, 52-54, 62-66, 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft in view of Eberlein (6856315). Kraft discloses the

invention substantially as claimed except for expressly disclosing wherein the pain level and concordance data is inputted separately by hand by the patient on a sliding device that is correlated to a visual analog scale (VAS) from 0-10 and includes an axis for relating level of concordance, non-concordance, or concordance and non-concordance of the pain.

20. Eberlein teaches that it is known to have wherein the pain level and concordance data is inputted separately by hand by the patient on a sliding device that is correlated to a visual analog scale (VAS) from 0-10 (406) and includes an axis for relating level of concordance, non-concordance, or concordance and non-concordance of the pain (420; Fig 4; wherein the axis of the body allows the patient to detail if the pain being currently experience appears at the same place as previous pain or if it is a new pain in a new place – thus concordance/non-concordance of pain may be entered and recorded) for the purpose of diagnosing a patient's pain condition. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Kraft with the pain level and concordance input as taught by Eberlein for the purpose of diagnosing a patient's pain condition.

Response to Arguments

21. Applicant's arguments filed 10/23/2007 have been fully considered but they are not persuasive.

22. The Applicant argues that:

i. Hochman et al does not disclose or suggest determining impedance data indicative of the flow rate-impedance based upon an actuation of an introducer prior to insertion of the introducer into the spine (Remarks, pg 11, paragraph 2).

23. In response to the Applicant's argument (i), the Examiner respectfully disagrees and notes that no agreement was reached during the interview of October 18th. It is clear from the disclosure of Hochman et al that while the system monitors the exit pressure and generates and maintains a specific flow rate even when there are changes in the resistance of the system (col 3, lns 39-43) the system of Hochman et al explicitly determines impedance data indicative of the flow rate-impedance prior to insertion into the spine (col 4, lns 23-35; col 7, lns 10-14; col 8, lns 43-60; col 9, lns 30-65). The determination of impedance data occurs as the syringe size, tube length, and various physical characteristics are entered by the physician and retrieved from the database. It is clear that this determination occurs during installation and priming of the syringe and is prior to the insertion of the introducer into the spine. The rejection is maintained.

ii. Kraft fails to disclose a computer readable medium having code for receiving concordance response data, input separately from pain level data, the concordance data indicating whether the pain level response of the patient is a result of a pain symptom or is a result of pain unrelated to the pain symptom (Remarks, pg 10, paragraph 4-pg 11, paragraph 1).

24. In response to the Applicant's argument (ii), the Examiner notes that the computer readable medium needs to be capable of receiving three types of data (fluid introduction, pain, and concordance) but there is no claim recitation that renders it necessary for the prior art to actually collect the data. Thus, if a prior art system is capable of receiving more than one set of data, or in the instance of Kraft - more than one set of audio/video data, in conjunction with fluid introduction data that are capable of being inputted separately from each other then the claim limitations are met. In the instant case, Kraft discloses computer readable medium having code for receiving fluid introduction data (col 3, lns 58-col 4, lns 13), response data indicative of pain level (col 4, lns 13-37), and is fully capable of receiving concordance data inputted separately. This could occur in many ways. For instance, the pain level could be recorded solely by visualizations of the patient's facial expressions and the concordance data could be inputted separately through audio recording of the patient's response to a medical officer prompted question "is your pain you feel now from your original pain symptom or is it a result of pain unrelated to the pain symptom?". In a separately instance, audio/video recordings could first be taken with the patient detailing the pain level at a time related to a time of the fluid introduction data and then next take a separate audio/video recording with the patient detailing the concordance of the response at the time related to the time of the fluid introduction data. Note that claim recitations do not necessitate that the concordance data must be inputted concurrently with the response data during fluid introduction into the patient. Additionally, note that Kraft's use of computer readable medium having code for audio/video input is fully capable of

receiving data in audio and video format on numerous patient response as the data is dependent on the patient's audio/visual response.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 5653739; 6387054; 5533514; 20020052562; 6529195.

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER